



Geoffrey W. Castello

Kelley Drye & Warren LLP
3 World Trade Center
175 Greenwich Street
New York, NY 10007

Tel: (973) 503-5922
Fax: (973) 503-5950
gcastello@kelleydrye.com

July 19, 2022

Via ECF

Hon. Louis L. Stanton, U.S.D.J.
United States District Court
Southern District of New York
500 Pearl Street
New York, NY 10007

Re: *FTC, et al. v. Quincy Bioscience Holding Co., Inc., et al.*
Case No. 1:17-cv-00124-LLS

Your Honor:

We represent defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC (collectively, “Quincy”), and Mark Underwood (together, with Quincy, “Defendants”). We write in response to Plaintiffs’ July 12, 2022 letter requesting a pre-motion conference. (Dkt. No. 283.) Plaintiffs’ request is nothing more than a last-ditch attempt to delay Defendants’ fully briefed motion for summary judgment (the “Pending Summary Judgment Motion”). One day after briefing on that motion was completed, Plaintiffs rushed to file a letter seeking leave to file a motion to exclude all seven of Defendants’ experts on various—and often unexplained¹—grounds. Plaintiffs cannot identify any actual flaws with Defendants’ experts that would warrant exclusion. This Court should therefore deny Plaintiffs’ request and rule on the Pending Summary Judgment Motion.

Although Plaintiffs alluded to the possibility that they would raise a *Daubert* challenge to Defendants’ experts in their opposition to the Pending Summary Judgment Motion, they did not do so. Instead, they waited until after briefing on that motion was complete and therefore waived any *Daubert* arguments in connection with that motion. *See U.S. v. DISH Network LLC*, 75 F. Supp. 3d 916, 919-20 (C.D. Ill. 2014) (*Daubert* motion was “untimely for purposes of summary judgment” when it was filed after summary judgment briefing was complete). In any event, the Pending Summary Judgment Motion does not turn on the admissibility of Defendants’ experts’ opinions; that motion is based on facts that cannot be disputed and the consequences that follow from Plaintiffs’ experts’ complete failure to apply (or even review) the relevant FTC standard (“competent and reliable scientific evidence”) and their

¹ Plaintiffs appear to be seeking to exclude testimony from all seven of Defendants’ experts, but their letter does not mention Drs. Dominik Alexander or Lee-Jen Wei, let alone explain why their opinions should be excluded.

July 19, 2022

failure to review evidence in connection with their reports. This court should therefore decide the Pending Summary Judgment Motion without considering Plaintiffs' untimely *Daubert* challenges.

Plaintiffs argue that “most” of Defendants’ experts—*they do not say which ones*—offer inadmissible opinions on the appropriate legal standard for substantiating the advertising claims at issue. Plaintiffs are wrong. Defendants’ experts are not offering legal conclusions; instead they explained what they understood the standard to be—the definition of “competent and reliable scientific evidence,” which comes directly from the FTC Guidance—and then evaluated Quincy’s scientific evidence against that standard. This consideration of the scientific evidence in light of the FTC Guidance is proper. An expert’s opinion must “fit” the case by speaking to the legal standards that govern the disposition of the case. To that end, expert testimony regarding compliance with a regulatory scheme is regularly admitted. *See In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 474 (S.D.N.Y. 2016) (“[C]ourts have consistently found that expert testimony regarding FDA regulations and a company’s compliance under that regulatory scheme is admissible.”); *FTC v. Garden of Life, Inc.*, 516 F. App’x 852, 857 (11th Cir. 2013) (“Since Weisman provided expert testimony that GOL did have competent and reliable scientific evidence to substantiate its claims, and the district court credited that testimony, we cannot discern clear error in the district court’s finding.”); *FTC v. Alcoholism Cure Corp.*, No. 3:10-CV-266-J-34, 2011 WL 13137951, at *27 (M.D. Fla. Sept. 16, 2011) (expert interpretation necessary to determine “what constitutes competent and reliable scientific evidence”), *aff’d sub nom. FTC v. Krotzer*, No. 12-14039-AA, 2013 WL 7860383 (11th Cir. May 3, 2013).

The opinions offered by Defendants’ experts are therefore entirely within the proper scope for expert opinions. Indeed, *both sides’* experts reviewed scientific evidence against a standard, with one critical difference: Defendants’ experts reviewed the evidence *in accordance with* the FTC Guidance, and Plaintiffs’ experts reviewed the same evidence *without even considering* the FTC Guidance. Plaintiffs’ argument on this point is thus a non-starter.

Dr. Mindy Kurzer. Plaintiffs argue that because Dr. Kurzer lacks expertise in fields related to memory or cognition, her review of the scientific evidence supporting the Challenged Claims is inadmissible. Specialization goes to weight, not admissibility. Dr. Kurzer was not offered as an expert on cognition. Dr. Kurzer offered an opinion as to whether the studies that substantiate the Challenged Claims constitute “competent and reliable scientific evidence.” Dr. Kurzer has a PhD in Nutritional Science, and has over three decades of experience performing her own research on dietary supplements and ingredients, teaching PhD students, and critically analyzing scientific literature. Indeed, in other cases, the FTC itself has defended against *Daubert* arguments using the same logic. *See FTC v. Your Baby Can LLC*, No. 3:12-CV-2114, 2014 WL 12789110, at *3 (S.D. Cal. Mar. 18, 2014) (“Plaintiff is not offering Dr. Dickinson as an expert on ‘infant learning’ and ‘teaching babies to read.’ Rather, Plaintiff is offering Dr. Dickinson as an expert on whether Defendants’ claims about its Program ‘are supported by competent and reliable scientific evidence.’”); *Idaho Wool Growers Ass’n v. Vilsack*, 7 F. Supp. 3d 1085, 1091 (D. Idaho 2014) (distinguishing between expertise in the subject matter at issue and expertise to review and assess scientific literature).

Dr. David Katz. Plaintiffs argue that Dr. Katz cannot have an opinion about the results of a statistical analysis because he did not conduct it. But Plaintiffs’ own cases confirm that courts look only to whether an expert can *interpret* the results of an analysis in forming an opinion. Plaintiffs point to *Hart v. BHH, LLC*, No. 1:15-CV-4804, 2018 WL 3471813 (S.D.N.Y. July 19, 2018), for the proposition that experts cannot pass off others’ opinions as their own. But the Court made clear that this doctrine applies only “when an expert is not qualified to interpret the ‘parroted’ results,” *id.* at *8, which is not

July 19, 2022

the case here. In addition to being a medical doctor, Dr. Katz had extensive training in biostatistics as part of his master's degree in public health, has served as the course director in biostatistics for Yale medical students, and has co-authored five editions of a textbook on epidemiology, biostatistics, and preventive medicine. He is unquestionably qualified to determine whether the results of the referenced SUR analysis bolstered his conclusion that the Madison Memory Study was "competent and reliable scientific evidence." In short, Dr. Katz did not pass off the opinion of others; he offered his own opinion.

Dr. Richard Goodman. Plaintiffs severely mischaracterize Dr. Goodman's opinions. Dr. Goodman does not opine on the efficacy of apoeaquorin. Rather, Dr. Goodman opined that apoeaquorin is non-allergenic and that Plaintiffs are misinterpreting the results of his lab's work. Dr. Goodman is more than qualified to offer that opinion: he has 40 years of experience in the fields of food science, allergenicity, and digestion and, unlike Plaintiffs' experts, was personally involved in the referenced allergenicity research on apoeaquorin.

Dr. David Gortler. Plaintiffs also distort Dr. Gortler's opinions. He is not offering an opinion on the Madison Memory Study. His rebuttal opinion responded to Plaintiffs' expert, Dr. Jeremy Berg, who opined that that for Prevagen to have an impact on memory, apoeaquorin must be absorbed into the bloodstream and cross into the brain. Dr. Gortler, a pharmacologist, explained not only that Dr. Berg presents an outdated and oversimplified view of mechanism of action, but also that dietary supplements, and even drugs, can have many different and often unknown mechanisms of action. And Dr. Gortler's discussion of Alzheimer's disease linked a cause of memory loss (excess calcium) and apoeaquorin's efficacy (its ability to bind and reduce calcium). Plaintiffs argue that such testimony is irrelevant because apoeaquorin is not used to treat Alzheimer's. Plaintiffs miss the point. Dr. Gortler does not suggest that it does or that needs to cross the blood-brain barrier. Plaintiffs' critiques are grounded in their expert's outdated mechanism-of-action theory and are not a basis to exclude Dr. Gortler's opinion. His opinions are backed up by decades of experience in pharmacology, including two stints with the FDA. They are relevant and supported.

Drs. Kurzer, Katz, and Schwartz Do Not Impermissibly Discuss Mechanism of Action. Dr. Kurzer explained that Prevagen's precise mechanism of action is not known with certainty. Dr. Katz does not offer an opinion on Prevagen's mechanism of action, noting only that Plaintiffs' position that there is no evidence that apoeaquorin crosses the blood-brain barrier does not equal established evidence that it does not (nor does it need to). And Dr. Schwartz noted that although Prevagen's mechanism of action is not definitively established, other supplements (and even approved drugs) with unknown mechanisms of action are widely considered to have well-established clinical benefits. These opinions are consistent with the FTC Guidance, which does not require a fully understood mechanism of action to substantiate marketing claims. All that is required is a *plausible* mechanism of action, which is exactly the subject of Defendants' experts' (Kurzer, Katz, Schwartz and Gortler) opinions.

For these reasons, Defendants respectfully request that the Court deny Plaintiffs' request for a pre-motion conference and defer consideration of any *Daubert* issues until after it decides the Pending Summary Judgment Motion.²

² To the extent the Court decides to consider *Daubert* issues now, Defendants will file their own request for a pre-motion conference to discuss their intended motion to exclude testimony from Plaintiffs' experts.

July 19, 2022

Respectfully submitted,

/s/ Geoffrey W. Castello

Geoffrey W. Castello
Kelley Drye & Warren LLP
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 808-7800
Fax: (212) 808-7897
gcastello@kelleydrye.com

*Counsel for Defendants Quincy Bioscience
Holding Company, Inc., Quincy Bioscience,
LLC, Prevagen, Inc. and Quincy Bioscience
Manufacturing, LLC*

cc: All Counsel of Record (via ECF)

/s/ Michael de Leeuw

Michael de Leeuw
Cozen O'Connor
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 908-1331
Fax: (212) 509-9492
mdeleeuw@cozen.com

*Counsel for Defendant
Mark Underwood*